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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/783,430 | 02/23/2004 | Janzen Lo | BBM-135US | 6316 |
| 23122 | 7590 | 09/20/2006 | EXAMINER | |
| RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980 | | | MCDERMOTT, CORRINE MARIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,430

Applicant(s)

LO ET AL.

Examiner

Corrine M. McDermott

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-12 is/are rejected.
- 7) ☒ Claim(s) 2, 8 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/23/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). In the instant case claim 7 is not present.

Misnumbered claims 8-23 have been renumbered as 7-22. Please note that within this Office action the claims are referenced using the new numbers.

Election/Restrictions

Applicant's election with traverse of claims 1-13 in the reply filed on January 13, 2006 is acknowledged. The traversal is on the ground(s) that the two sets of claims should be considered as directed to the same invention of the gauge block. This is not found persuasive because, as set forth in the previous Office action, the claimed apparatus is found to be distinct from the claimed method because it does not require determining the space between two vertebrae, and as such, could be used as a permanent spinal disc replacement implant.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 13, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGahan et al. 6,984,245 in view of Krueger et al 2004/0133279.

With reference to figures 1 and 2a, McGahan et al. teach a tapered intervertebral disc implant reading on the spinal gauge block as claimed. The disc implant has a top surface 12, a bottom surface 14, and a side surface intermediate the top and bottom surfaces with two threaded side holes 40, 44 and a bore 42 extending therethrough. McGahan further teaches a tool 80 (figures 5, 6, 8 and 9) used to insert the implant from multiple approaches to the spine having a sleeve portion 82 with a rotatably threaded portion 85 therein and a pin 92 that provides for a non-rotation connection with bore 42. In accordance with column 11 lines 23-25 the holes can be angled at any oblique angle. McGahan et al. do not teach, however, indicia on the implant marking the location of the greater dimension of the taper and aligned with the axis of one of the two threaded holes.

Krueger et al. teach, with reference to figure 5, a tapered intervertebral disc implant 30. As noted in paragraph 0047 the implant may include an indicator that allows the installer to distinguish the anterior side from the posterior side. With specific reference to lines 12-14 of that same paragraph, it is further stated that the indicator may be indicia that is printed, etched, or marked on a surface, e.g. side 36, the side with the greater dimension. Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have modified the disc implant of McGahan by providing indicia on the side of greater dimension for the purpose of distinguishing for the installer the anterior side of the implant from the posterior side of the implant. It should further be noted that by placing such indicia on wall 18 of the McGahan implant, the wall with the greater dimension, the axis of one of the threaded holes would inherently be aligned with the indicia while the other would be at an angle to it.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGahan et al. in view of Krueger et al. as applied to claims 1 and 3 above, and further in view of Pafford et al. 6,371,988

McGahan et al. as modified by Krueger et al. discussed supra, disclose an intervertebral disc implant, reading on the spinal gauge block as claimed, in combination with a tool assembly. Not taught, however, are markings along the tool for determining the depth of penetration of the tool into the patient's body.

Pafford et al. teach an intervertebral disc implant 20 used with an implant driver 60 (figure 9) to insert the implant into the spine. In accordance with column 9 lines 43-

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45, it is noted that the depth of insertion of the fusion spacer (disc implant) into the spine can be ascertained using depth markings on the implant driver. Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have modified the tool of McGahan et al. by providing it with depth markings for the purpose of aiding the installer in ascertaining the depth of insertion of the disc implant into the spine.

Allowable Subject Matter

Claims 2, 8 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

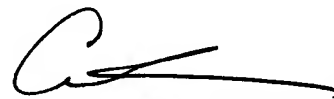
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Garcia 2003/0139812 provides another example of depth markings on an implant inserter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Corrine M. McDermott whose telephone number is (703) 308-2111. The examiner can normally be reached on Monday through Friday from 8 am to 4 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Corrine M. McDermott
SPE
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